


JC07 Rec'd PCT/PTO 12 APR 2005 #4

Date: April 11, 2005 I hereby certify that, on the date indicated above, I deposited this paper with identified attachments and/or fee with the U.S. Postal Service and that it was addressed for delivery to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 by "First Class Mail" service.

Donald S. Prater  
Name (Print)

  
Signature

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	SATO et al.	)	Examiner:	Unassigned
		)		
Application No.:	10/524,278	)	Group Art Unit:	Unassigned
		)		
Filed:	February 9, 2005	)	Confirmation No.:	Unassigned
		)		
Docket No.:	3190-074	)	Customer No.:	33432

For: METHOD FOR PREDICTING DRUG METABOLIZING ACTIVITY BY ANALYSIS OF  
GLUCURONOSYLTRANSFERASE GENE MUTATION

**INFORMATION DISCLOSURE STATEMENT**  
**PURSUANT TO 37 CFR 1.97(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

April 11, 2005

Sir:

The attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached Form PTO-1449. Pursuant to the current United States Patent and Trademark Office rules, no copies of U.S. Patents/Patent Application Publications are provided.

This Information Disclosure Statement is being submitted before expiration of the three-month period following filing of the above-captioned application.

The above information is presented so that the Patent and Trademark Office can, in the first instance, determine any materiality thereof to the claimed invention. See 37 CFR 1.104(a) and 1.106(b) concerning the PTO duty to consider and use any such information. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the documents cited in the attached Form PTO-1449 be made of record therein and appear

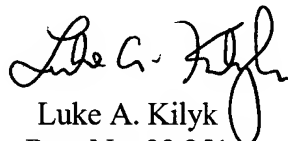
on the first page of any patent to issue therefrom.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in this application and applicant determines that the cited documents do not constitute "prior art" under United States law, applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant further reserves the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

It is believed that no fee is required to make this a complete and timely filing. However, if it is determined that a petition or fee is required, the Commissioner is hereby authorized to charge any fee associated with this statement to our Deposit Account No. 50-0925.

Respectfully submitted,

  
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Atty. Docket No.: 3190-074  
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Enclosures: Form PTO-1449 and 9 documents

FORM PTO-1449 (REV. 10-00)	Atty. Docket No. 3190-074	Application No. 10/524,278
<b>INFORMATION DISCLOSURE STATEMENT</b>	APPLICANT: SATO et al.	
	Filing Date: February 9, 2005	Group Art Unit: Unassigned

APR 12 2005

**U.S. PATENT DOCUMENTS**

EXAMINER'S INITIALS	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE, IF APPROPRIATE

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION YES NO	

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	Ito et al., "Effect of a Conserved Mutation in Uridine Diphosphate Glucuronosyltransferase 1A1 and 1A6 on Glucuronidation of a Metabolite of Flutamide," EUR. J. CLIN. PHARMACOL., Vol. 58, No. 1, pp. 11-14 (2002)
	Yamamoto et al., "Contribution of Two Missense Mutations (G71R and Y486D) of the Bilirubin UDP Glycosyltransferase (UGT1A1) Gene to Phenotypes of Gilbert's Syndrome and Crigler-Najjar Syndrome Type II," BIOCHIM. BIOPHYS. ACTA., Vol. 1406, No. 3, pp. 267-273 (1998)
	Ando et al., "Polymorphisms of UDP-Glucuronosyltransferase Gene and Irinotecan Toxicity: A Pharmacogenetic Analysis," CANCER RESEARCH, Vol. 60, pp. 6921-6926 (2000)
	Ando et al., "Polymorphisms and UDP-Glucuronosyltransferase and Pharmacokinetics of Irinotecan," THERAPEUTIC DRUG MONITORING, Vol. 24, pp. 111-116 (2002)
	Owens et al., "The Novel UGT1 Gene Complex Links Bilirubin, Xenobiotics, and Therapeutic Drug Metabolism by Encoding UDP-Glucuronosyltransferase Isozymes With a Common Carboxyl Terminus," JOURNAL OF PHARMACOKINETICS AND BIOPHARMACEUTICS, Vol. 24, No. 5, pp. 491-508 (1996)
	Jinno et al., "Glucuronidation of 7-Ethyl-10-Hydroxycamptothecin (SN-38), an Active Metabolite of Irinotecan (CPT-11), by Human UGT1A1 Variants, G71R, P229Q, and Y486D," DRUG METABOLISM AND DISPOSITION, Vol. 31, pp. 108-113 (2003)
	Gagné et al., "Common Human UGT1A Polymorphisms and the Altered Metabolism of Irinotecan Active Metabolite 7-Ethyl-10-Hydroxycamptothecin (SN-38)," MOLECULAR PHARMACOLOGY, Vol. 62, pp. 608-617 (2002)
	Chang et al., "Metabolism of Flutamide in Diet Control Fischer 344 and Brown Norway x F 344 Rats, and Its Hydroxylation and Conjugation by Human CYP450s and UDP-Glucuronosyltransferases," JOURNAL OF FOOD AND DRUG ANALYSIS, Vol. 8, No. 3, pp. 166-173 (2000)
	International Search Report for PCT/JP03/01475 mailed May 6, 2003

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.